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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/928,272 | 09/12/97 | ISKRA | M P-3818 |

QM22/0614
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EXAMINER

PATEL, M

ART UNIT

PAPER NUMBER

3761

19

DATE MAILED: 06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-----------------|-------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 08/928,272 | ISKRA, MICHAEL J. | |
| | Examiner | Art Unit | |
| | Mital B. Patel | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 4/4/01 have been fully considered but they are not persuasive.
2. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).
3. The Examiner maintains that it would have been obvious to one of ordinary skill in the art to modify the false bottom end of Burns to that with an arcuate shoulder depending on the intended use. Collection tubes which have an arcuate shoulder shaped bottom are known in the art and therefore such a modification to Burns would be well within the scope of one of ordinary skill in the art so that the Burns collection assembly is compatible with standard clinical equipment and instrumentation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (5458854).

6. As to claim 1, Burns teaches a one-piece collection container assembly comprising an elongate tubular housing having opposed first and second ends and a cylindrical wall therebetween defining a tubular interior (See Figure 1); and a solid partition (38) positioned within the housing between the first and second ends; the housing defining a volume for specimen collection therein between the first end and the partition; the second end comprising a false bottom end comprising an open bottom end (47). It should be noted that Burns fails to specifically teach a false bottom end wherein the open bottom end is rounded and extending from an arcuate shoulder. However, it would have been obvious to one of ordinary skill in the art to modify the bottom end of Burns so that it is arcuate depending on the intended use, i.e., if the intended use is with standard clinical equipment and instrumentation which support a rounded and arcuate shaped bottom, then it would be well within the scope of one of ordinary skill in the art to modify the collection assembly of Burns so that it is more compatible with the standard equipment.

7. As to claim 5, Burns teaches an assembly wherein the partition is arcuate in shape to provide the volume for specimen collection with at least a partially rounded bottom portion.

8. As to claim 6, Burns fails to specifically teach an assembly wherein the partition is conical in shape. However, the shape of the partition is a mere design choice that can be obtained through routine observation and experimentation. Furthermore, the Applicant fails to

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disclose why one particular shape would be advantages over another or what particular purpose is served by a conical shaped partition.

9. As to claim 7, Burns teaches an assembly wherein the housing is a thermoplastic polymer.

10. As to claim 8, Burns teaches an assembly wherein the thermoplastic polymer is polyethylene terephthalate, polypropylene, polyethylene naphthalate, polyvinyl chloride or copolymers thereof.

11. As to claim 9, Burns fails to specifically teach an assembly wherein the housing has the particular dimensions as set forth by the claim. However, the Applicant fails to disclose why those particular dimensions are advantageous or what particular problem those specific dimensions solve. Furthermore, depending on the intended use, e.g., how much sample is to be collected, the dimensions of the housing will vary and such dimensions may also be derived through routine observation and experimentation.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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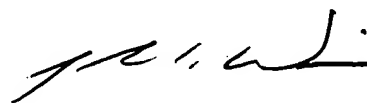
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 703-308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
June 13, 2001



John G. Weiss
Supervisory Patent Examiner
Group 3700